UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA

THE CITY OF HUNTINGTON, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION, *et al.* Defendants.	Civil Action No. 3:17-01362 Honorable David A. Faber
CABELL COUNTY COMMISSION, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION, *et al.* Defendants.	Civil Action No. 3:17-01665 Honorable David A. Faber

DEFENDANTS' MOTION TO EXCLUDE
CERTAIN EXPERT TESTIMONY OF KATHERINE KEYES

Introduction

Defendants seek the exclusion of two opinions proffered by Dr. Katherine Keyes, an epidemiologist retained by Plaintiffs. In the opinions at issue, Keyes uses unreliable principles and methods (1) to re-classify as "directly" attributable to prescription opioids overdose deaths that a medical examiner identified as having occurred in part because of illicit fentanyl or heroin poisoning; and (2) to extrapolate an unreliable estimate of the Cabell County population suffering from an opioid use disorder ("OUD") while ignoring available data. On both issues, Keyes' opinions are unreliable and inadmissible.

The opinions at issue in this motion are not the subject of any prior *Daubert* motions or rulings, and they have not previously seen the light of any courtroom. Neither are they grounded in academic literature, or capable of being tested. They are the product of methodologies specially created for this litigation, with only Keyes' say-so to validate their reliability. Because these opinions are "connected to existing data only by the *ipse dixit* of the expert," *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997), they should be excluded.

Background

This *Daubert* motion concerns two opinions of Keyes that should be excluded:

1. The first opinion concerns the number of overdose deaths attributable to ***prescription*** opioids as distinct from illicit fentanyl and heroin.[1] Plaintiffs evidently recognize that it is a stretch to seek to hold Defendants responsible for addiction and death caused by the use of illegal fentanyl or heroin. Accordingly, through Keyes, they seek to re-classify illicit fentanyl and heroin poisoning deaths as prescription opioid deaths, in two ways. First, Keyes literally re-labels them, taking overdose deaths identified by a medical examiner as having been contributed to by ***both*** prescription opioids ***and*** illicit fentanyl or heroin and then re-classifying them as deaths caused "directly" by prescription opioids. This opinion is outside the scope of Keyes' expertise, illogical, and not helpful to the determination of any relevant fact. Second, in an opinion that Keyes already has changed twice (most recently, following her deposition), Keyes estimates a certain number of fentanyl-involved overdose deaths as having resulted from

[1] For simplicity, Defendants use the term illicit fentanyl to describe the category of synthetic opioids that also includes substances that are "in the fentanyl chemical family, but have minor variations in chemical structure (e.g., acetyl fentanyl, furanyl fentanyl, carfentanil)." App. 225 (DEA 2019 National Drug Threat Assessment ("NDTA")), at p. 18 fn "i".

prescription fentanyl rather than illicit fentanyl. But Keyes has failed to disclose any of the information required by Rule 26 for her latest opinion, necessitating that opinion's exclusion.

2. The second opinion concerns the number of persons who have OUD—the disorder that lay persons would refer to as opioid addiction or dependency. There is no way for Keyes to count those persons directly, so she extrapolates the number of those with OUD from the number of overdose deaths. As explained below, Keyes greatly understates the lethality of fentanyl, which accounts for most overdose deaths, and therefore greatly overestimates the number of opioid-addicted and dependent residents.

ARGUMENT

I. Keyes' Opinion on the Overdose Deaths Caused "Directly" by Prescription Opioids is Unreliable and Inadmissible.

Keyes seeks to testify to the number of Cabell County overdose deaths "due directly to Prescription Opioids" as well as the number of overdose deaths from ***illicit*** substances that, according to her, are "attributable to Prescription Opioids" indirectly.[2] Keyes' opinions on those subjects are in turn adopted by Dr. McGuire, who purports to measure the net economic costs of the sale and distribution of opioids in Cabell County. Since submitting her report in early August, Keyes has twice revised it, with the effect that her estimate of 2018 overdoses "directly attributable" to Prescription Opioids has decreased from 104 originally, to 32 in late August, and currently stands at 20. Simultaneously, her estimate of 2018 overdoses from other illicit substances that are nevertheless "indirectly attributable to" Prescription Opioids has increased

[2] App. 128-130 (Keyes Rpt. 33–35 & Figure 8); App. 143-145 (*id.* at 48–50 & Figure 16); App. 166 (Keyes First Errata (8/24/20) at 3); App. 167 (Keyes Second Errata (9/23/20) at 1).

from 1 originally, to 39 in late August, and currently stands at 45.[3] These revisions have likewise led to multiple revisions of McGuire's corresponding calculations.

Keyes's calculation of deaths that are "directly" the result of Prescription Opioids is unreliable, outside her qualifications as an expert, and will not assist the Court.

A. Keyes' Count of Overdoses "Directly" Caused by Prescription Opioids is Unreliable and Unhelpful to the Court.

In counting the overdose deaths caused "directly" by prescription opioids, Keyes begins by re-classifying deaths caused at least in part by illicit fentanyl or heroin as deaths caused by prescription opioids ***alone***.[4]

By way of background, overdose deaths are classified by medical examiners using codes promulgated by the World Health Organization.[5] When multiple substances are present, the death certificate may include multiple codes. So, for example, decedents who had both heroin and a prescription opioid in their system at the time of death could have codes for both heroin and prescription opioids on their death certificates, and with both prescription methadone and illicit fentanyl could have codes for both prescription methadone and illicit fentanyl on their death certificates. Keyes testified that in such cases of multiple drug use, she, as a rule, counted the death as having been caused "directly" by a prescription opioid, and not as caused by the heroin and/or fentanyl that was also present: "Q. [I]f prescription opioids were listed as one of

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[3] *Id.* Discussed here for simplicity are just the 2018 annual figures. Keyes presents annual versions of these statistics back to 2006.

[4] App. 128 (Keyes Rpt. 33); App. 47-48 (Keyes Dep. 183:22–186:2); App. 49 (*id.* at 191:10–18); App. 85 (*id.* at 334:4–10).

[5] The International Statistical Classification of Diseases and Related Health Problems ("the ICD-10" codes) provide different codes for deaths caused by heroin ("T40.1"), prescription opioids ("T40.2"), methadone and other semi-synthetic opioids ("T40.3"), and synthetic opioids such as fentanyl ("T40.4").

the contributing factors, you directly attributed the death to prescription opioids even if there were other drugs also identified as contributing causes? A. That's right."[6]

In this way, Keyes systematically overstates the number of overdoses purportedly caused by prescription opioids, and understates the number caused at least in part by illicit fentanyl and heroin. Although the percentage varies from year to year, ***as much as 75%*** of the overdoses that Keyes identifies as caused "directly" by prescription opioids were also caused by either heroin or illicit fentanyl.

Keyes tries to justify this revisionism by saying that each substance represented by a code on a death certificate was "necessary for the death" to occur.[7] But Keyes lacks the expertise to say that, and her assertion is unfounded. If each substance was necessary for a death to occur, then each overdose death also coded with heroin or fentanyl would not have occurred but for the decedent's use of illicit fentanyl or heroin. The prescription opioid that Keyes identifies as having "directly" caused those deaths would alone have been insufficient, under Keyes' logic.

Illogic aside, Keyes is wrong and does not have the expertise to opine that a person who overdosed from a combination of prescription opioids and illicit fentanyl would not have overdosed from the fentanyl alone. Fentanyl is vastly more potent and dangerous than either prescription opioids or heroin – a mere two milligrams (equivalent to a few grains of table salt) is

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[6] App. 47-48 (Keyes Dep. 185:20–186:2); *see also* App. 49 (*id.* at 191:10–18); App. 85 (*id.* at 334:4–10).

[7] App. 48 (Keyes Dep. 187:12–188:2); *see also* App. 49 (*id.* at 190:8–22) ("The definition of 'cause' is a factor without which the outcome would not have occurred. … There can be multiple causes, but it's not a cause unless the outcome would not have occurred without it.").

considered to be a lethal dose.[8] That is why fentanyl is "involved in more deaths than any other illicit drug" and is characterized by the DEA as "the most lethal category of illicit substances misused in the United States."[9]

Keyes holds no medical degree and has no experience as a medical examiner.[10] While she touts her training as an epidemiologist as giving her expertise in "evaluating the reliability and validity of" the causes of death identified by medical examiners,"[11] nothing in the field of epidemiology equips Keyes to examine death certificate data identifying heroin or fentanyl as a contributing cause of death and determine instead that the death occurred "directly" as the result of a prescription opioid. Moreover, even if Keyes had expertise adequate to conduct such an analysis, she has employed no scientific methodology to determine the relative impact of prescription opioids versus heroin or fentanyl in causing any particular death. Instead her "method," such as it is, is self-servingly to characterize the death as caused by the product Defendants distribute, and not by the product distributed by illegal drug cartels. Such an analysis fails Rule 702's reliability requirement. *See, e.g., Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 590 (1993) (Rule 702 bars opinions that are the product of "subjective belief or unsupported speculation"); *In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1041-42 (D. Minn. 2007) (excluding epidemiologist's opinion on the "comparative toxicity" of different drugs because it was not the product of a reliable scientific method).

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[8] App. 222 (2019 DEA NDTA, at p. 15); App. 143 (Keyes Rpt. 48). The DEA vividly illustrates this amount by showing the size of a fatal dose of fentanyl adjacent to a penny. *See* App. 228.

[9] App. 216 (2019 DEA NDTA, at p. 9) (first quote), App. 213 (*id.* at 5) (second quote).

[10] App. 99 (Keyes Rpt. 4); App. 47 (Keyes Dep. 182:7–12).

[11] App. 47 (Keyes Dep. 182:19–183:2).'

The Court also should exclude Keyes' tally of deaths caused "directly" by prescription opioids because it is not helpful to the determination of any relevant fact. *See Daubert*, 509 U.S. at 591-92. By definition, the abuse of prescription opioids in combination with heroin or illicit fentanyl is a form of illegal behavior. No relevant fact is made more probable by taking an overdose death that, according to the medical examiner, was in part caused by heroin or illicit fentanyl and re-labeling that overdose as a death caused "directly" by prescription opioids. Such an opinion only has the capacity to mislead the Court, by masking the contribution of heroin or illicit fentanyl to causing the death.

B. Keyes' Attribution of Certain Synthetic Opioid Deaths to Prescription Opioids Should Also Be Excluded Because Her Full Method Has Not Been Disclosed.

Keyes' count of the overdose deaths "directly" attributable to prescription opioids should be excluded for the additional reason that she uses an undisclosed methodology to attribute a certain number of fentanyl deaths to prescription fentanyl, and includes this amount within her total count of overdoses caused "directly" by prescription opioids. Because Keyes' method has not been disclosed, she may not testify to those results. *See* Fed. R. Civ. P. 37(c).

What's more, Keyes' opinion on this point has changed several times, including most recently on September 23, more than a week following her deposition. To aid in the Court's understanding of Keyes' failure to make the requisite disclosure, Defendants will briefly summarize the evolution of her opinion before addressing why these circumstances require exclusion.

1. Keyes' Opinion Prior to and During Her Deposition.

In her report, Keyes explains that the emergence of illicit fentanyl in 2013 confounded her ability to count overdose deaths caused by prescription opioids, because overdoses from

prescription fentanyl were (and are) coded the same as those caused by illicit fentanyl.[12] Accordingly, Keyes described a methodology by which she calculated a "***rate*** of synthetic opioid overdose deaths from 1999 to 2012, and applied that rate to synthetic opioid overdose deaths from 2013 and onwards as an estimate of the number of synthetic opioid overdose deaths that are reasonably attributable to prescription opioids."[13]

Importantly, as Keyes testified, this approach means that no matter how many "synthetic" (i.e., fentanyl) opioid overdoses occurred in a given year after 2013, Keyes would attribute a fixed percentage of those deaths to prescription fentanyl: "So as an example, if prior to 2013 there were 100 ***prescription opioid*** deaths and two of them were ***prescription fentanyl*** deaths, if there were 100 ***fentanyl deaths*** after 2013, I would estimate that two of those would be ***prescription fentanyl*** deaths."[14] This is an apples-to-oranges comparison.[15]

When asked to explain the logic of the calculation, Keyes responded with the *ipse dixit* assertion that she multiplied her ratio against fentanyl deaths "because those are the deaths that I

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[12] App. 128 (Keyes Rpt. 33).

[13] App. 128 (Keyes Rpt. 33).

[14] App. 89 (Keyes Dep. 352:18–353:5). Keyes agreed that if, instead, of 100 deaths there were 400 fentanyl deaths after 2013, her approach would consider eight of them to have resulted from prescription fentanyl. App. 89 (*id.* at 353:6–15). And on and on. No matter how many "synthetic" deaths occurred, Keyes' ratio "stays the same" and attributes a fixed percentage to prescription fentanyl, App. 89-90 (*id.* at 353:16–354:7), notwithstanding that the availability of prescription fentanyl "decreased slightly" in this period, as Keyes acknowledged. App. 92 (*id.* at 364:24–365:3).

[15] In particular, Defendants intended to show that Keyes applied the ratio that answered one question—"Out of all ***prescription opioid*** overdose deaths, what proportion are caused by prescription fentanyl?"—to the very different question—"Out of all ***fentanyl deaths***, what proportion are caused by prescription fentanyl?" That is akin to calculating the ratio of all food poisonings at the ballpark caused by hot dogs, then applying that ratio to answer the question of how many food poisonings from hot dogs were caused by kosher hot dogs.

was interested in identifying an estimate of the number that would be due to prescriptions."[16] When asked a second time how her method was remotely capable of providing the answer to that question, Keyes ultimately responded: "It's a relatively moot point, because I did it a number of different ways, and the results were robust to the type of correction that you did."[17]

During her deposition, Keyes expressed significant uncertainty over how this aspect of the calculation was performed. When asked whether she had prepared the calculation herself, Keyes responded that she worked on it with a "research assistant."[18] When asked whether she had even a working understanding of how the calculation was performed, Keyes replied: "No, to be honest with you, I don't."[19]

2. Keyes' Post-Deposition Revised Opinion.

On September 23, Plaintiffs served a further errata (Keyes' second) revising her opinion as to the number of overdose deaths caused "directly" by prescription opioids.[20] It is evident from the revised figures that Keyes no longer is using the fixed ratio disclosed in her report and discussed at length in her deposition testimony. Instead of an annual number that rises or falls as synthetic opioid overdoses rise or fall, Keyes now appears to attribute three overdose deaths annually to prescription fentanyl for the years 2013 to 2018. The errata includes no text accompanying this change. Accordingly, Plaintiffs and Keyes have not explained ***why*** Keyes' opinion changed, ***what*** the basis is for her new opinion, or ***what*** methodology she used to

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[16] App. 89 (*id.* at 352:13–17).

[17] App. 89-90 (*id.* at 352:18–354:5).

[18] App. 86 (Keyes Dep. 340:1–3).

[19] App. 86 (Keyes Dep. 340:9–14).

[20] *See* App. 167 (Keyes' Second Errata).

identify the number of prescription fentanyl overdose deaths that occurred in the years 2013 to 2018. And, because Plaintiffs did not make corresponding changes to the relevant portions of Keyes' opinions, the numbers disclosed in Keyes' second errata do not match the corrected Figure 16 in her first errata,[21] and neither do they correspond to the textual explanation of her methodology contained on page 33 of her report. Keyes thus is offering a free-floating conclusion in violation of Rules 26(a)(2)(B) and 37(c).

Rule 26 mandates the disclosure of the "basis and reasons" of an expert's opinions. *See* Fed. R. Civ. P. 26(a)(2)(B)(i). Where, as here, an expert for a party fails to satisfy these disclosure requirements, Rule 37(c) further provides "the party is not allowed to use that information or witness to supply evidence … at a trial, unless the failure was substantially justified or is harmless." *Id.* Rule 37(c)(1). "Of importance here, Rule 26(e)(1) requires a party to supplement its experts' reports and deposition testimony when the party learns of new information." *Southern States Rack and Fixture, Inc. v. Sherwin-Williams, Co.*, 318 F.3d 592, 595-96 (4th Cir. 2003). "If the party fails to do so, the court may exclude any new opinion offered by the expert." *Id.* at 596. "While Rule 37(c)(1) requires the nondisclosure to be 'without substantial justification' and harmful, neither of these requirements suggests that the nondisclosing party must act in bad faith or otherwise culpably." *Id.*

Exclusion is appropriate here. Having already corrected this opinion once via an errata, Keyes sat for a deposition in which she described her opinion at length, but struggled to explain or justify it. Eight days later, without explanation, Keyes changed her opinion without disclosing any of the information required by Rule 26. If Keyes did not understand the calculation prepared by her research assistant and is unwilling to defend it, she should have said so. If her opinion has

[21] *See* App. 166 (Keyes' First Errata, at p. 3).

changed and she now believes a different methodology is appropriate, she should have described that methodology and explained in the errata what she believes it to show. Instead, she merely provided a bottom-line conclusion with no surrounding text or explanation. That the disclosure comes after her deposition and on the eve of trial makes prejudice to the defense unavoidable.

II. Keyes' Estimate of the Number of Opioid-Addicted Persons in Cabell County Is Unreliable and Inadmissible.

Keyes "estimated the number of individuals with opioid use disorder (OUD) in … Cabell County in order to obtain an estimate of the number who should have access to services to treat OUD …."[22] Estimating this number, she acknowledged, was a "challenge," because "there is no systematic way to count this population."[23] The method Keyes used to make an estimate was what she calls "the multiplier method"—in effect, an extrapolation from the number of opioid deaths in Cabell County during 2018 to the number of county residents with OUD. Her method and conclusion are entirely unreliable.

The mathematical formula Keyes uses involves dividing the known number of drug overdoses in Cabell County (115 in 2018) by an estimate of the drug-related mortality rate among people using opioids "extramedically" (0.52 per 100 person-years, or 0.0052) stated in an academic paper.[24] But this calculation required correction, Keyes recognized, because (i) the opioid mortality rate of 0.52 per 100,000 was taken from a meta-analysis involving 124 studies that were conducted well before illicit fentanyl became the primary cause of opioid-overdose

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[22] App. 136 (Keyes Rpt. 41).

[23] *Id*.

[24] App. 137 (*id*. at 42) ("Given an event rate of 0.52 per 100,000, we can estimate the number of people who have OUD if we know the number of drug overdoses in a particular area, and divide that number by 0.52 per 100,000 …."); *id*. ("the number of drug overdoses in 2018 … is 115").

deaths,[25] and (ii) illicit fentanyl is more deadly than prescription opioids or heroin. The need to adjust the mortality rate upward follows from the truism that the more deadly a drug, the fewer the number of persons who need to use it in order to reach a certain number of overdose deaths.

Assume, for example, that the mortality rate for prescription opioids is 0.5 per 100,000, the rate for fentanyl is six times greater, 3 per 100,000, and the number of overdose deaths in the county is 100. Assuming that prescription opioids were the only source of opioids and using the lower mortality rate for prescription opioids, the estimated number of "extramedical" users in the county would be 20,000 (100 ÷ 0.005 = 20,000), whereas if fentanyl were the only source, the estimated number of "extramedical" users would be only 3,333 (100 ÷ 0.03 = 3,333). Thus, it is important to get the mortality rate for fentanyl use right. As Keyes testified, all else being equal, the higher the overdose rate for fentanyl, the smaller the OUD population she estimates through this "multiplier method."[26] Keyes' use of the "multiplier method" to estimate Cabell County's OUD population is unreliable and inadmissible for multiple reasons.

A. Keyes Ignores Relevant Data.

Keyes does not use current data. She states that "the estimated overdose event rate from synthetic opioid use [i.e., fentanyl] is approximately three times that of heroin based on available literature (the overdose rate due to heroin and synthetic non-methadone opioids increased by a factor of three ***from 2011 to 2015***)."[27] As a result, Keyes adjusted her multiplier for synthetic

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[25] *Id*. (citing Larney S, Tran LT, Leung J, et al., *All-cause and cause-specific mortality among people using extramedical opioids: a systematic review and meta-analysis*, JAMA Psychiatry (Dec. 2019)).

[26] App. 80 (Keyes Dep. 315:22–317:1).

[27] App. 137 (Keyes Rpt. 42). Specifically, Keyes relied upon data showing that from 2011 to 2015 the overdose death rate for heroin and fentanyl increased from approximately 2 per 100,000 people to 6 per 100,000. App. 83 (Keyes Dep. 326:17–24).

opioid overdose deaths by a factor of three. But, in fact, one of the sources of data that Keyes cited in support of that very contention[28] shows that from 2015 to 2016, the synthetic opioid overdose rate for ***fentanyl alone*** doubled from 3.1 per 100,000 to 6.2; that it further increased from 2016 to 2017 (from 6.2 to 9.0 per 100,000); and that it increased again from 2017 to 2018 (from 9.0 to 9.9 per 100,000).[29] These and other data[30] reflect an exponential increase in fentanyl deaths from 0.8 per 100,000 in 2011 to 9.9 per 100,000 in 2018, a ***more than twelvefold increase***, not the mere tripling claimed by Keyes. And for West Virginia specifically, the synthetic opioid fatality rate was higher still: 34 per 100,000 in 2018, the highest in the country,[31] and ***more than forty times*** higher than the nationwide rate before the introduction of illicit fentanyl.

Keyes testified that she was generally aware of the increasing overdose death rate from fentanyl after 2015, and deliberately did not include that information in her analysis.[32] According to Keyes, the increase in synthetic opioid overdose deaths from the years 2011 to 2015 is the relevant measure "[b]ecause that covers the direct pre- and post-fentanyl introduction. … If you went through 2018, you would get a much bigger factor, but that

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[28] *See* App. 137 (Keyes Rpt. 42) (citing reference 194); App. 160 (*id.* at 65) (identifying reference 194 as: Centers for Disease Control and Prevention. Synthetic opioid overdose data. 2019. https://www.cdc.gov/drugoverdose/data/fentanyl.html); App. 83 (Keyes Dep. 326:8–16) (same).

[29] *See* App. 177 (replication of CDC website cited by Keyes as reference 194).

[30] *See* App. 179 (CDC data table) at p. 3 (full data table available at https://www.cdc.gov/drugoverdose/data/fentanyl.html); *see also* App. 220–21 (2019 DEA NDTA, at pp. 13–14 and Figure 7).

[31] *Id.*

[32] *See* App. 83 (Keyes Dep. 327:1–328:2).

wouldn't be relevant to the multiplier that I was interested in."[33] She acknowledged, however, that this required her to make the "assum[ption] that the contribution of synthetic opioids in terms of the percentage increase in drug overdose death was similar after 2015"—i.e., that the risks of overdosing from fentanyl did not increase after 2015.[34] But that assumption is based on nothing; Keyes testified that she did not investigate whether there had been changes since 2015 in the ways in which illicit fentanyl is made or sold that make it more dangerous today.[35]

In fact, there is abundant data—consistently ignored by Keyes—that the risks of a fentanyl (or fentanyl analog) overdose is greater today than it was in 2015.[36] That greater risk is borne out in the markedly higher fentanyl overdose death rates of 2018 compared to 2015—particularly in West Virginia, which had the highest rate in the country and orders of magnitude greater than the multiple used by Keyes.[37] Yet, Keyes applied a multiplier based on an outdated ***2015*** overdose death rate for ***both*** heroin and fentanyl to the number of ***2018*** Cabell County

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[33] App. 81 (Keyes Dep. 318:11–19).

[34] App. 82 (Keyes Dep. 323:7–10).

[35] App. 81 (Keyes Dep. 319:2–321:4).

[36] Among other things, the powerful elephant tranquilizer carfentanil (a substance 10,000 times more powerful than morphine) was not available prior to 2016, but by 2017 had become the second most common synthetic opioid abused. App. 188 (2017 DEA NDTA, at p. 62); App. 196, 2018 DEA NDTA, at p. 23, Figure 30; App. 218 (2019 DEA NDTA, at p. 11). For another, fentanyl increasingly is being mixed with other substances, which Keyes testified increases the risks of an overdose. *See* App. 48-49 (Keyes Dep. 187:12 – 190:7); *see also* App. 220 (2019 DEA NDTA, at p. 13) ("Between 2016 and 2017, the number of reports of fentanyl and heroin increased 97 percent; the number of reports of fentanyl and cocaine increased 74 percent; and the number of reports of fentanyl with methamphetamine increased 173 percent.").

[37] *See* App. 177 (full data table available at https://www.cdc.gov/drugoverdose/data/fentanyl.html); *see also* App. 220–21 (2019 DEA NDTA, at pp. 13–14 and Figure 7).

overdose deaths from fentanyl ***alone*** in order to estimate the population with OUD in ***2018***.[38] Had she instead used a multiplier based on the 2018 synthetic opioid data cited in her report, her OUD estimate would have been substantially lower.[39] Nothing but Keyes' *ipse dixit* supports the reliability of mixing and matching data from these different substances (heroin plus fentanyl versus fentanyl alone) and different time periods (2015-based multiplier against 2018 fentanyl overdose deaths).

In *Joiner*, the Supreme Court held that nothing in the Federal Rules of Evidence requires a court to admit opinion testimony that is connected to existing data only through the *ipse dixit* of an expert. *Joiner*, 522 U.S. at 146. Likewise, in *In re C.R. Bard, Inc.*, a judge of this Court excluded multiple expert opinions that were "lacking in any reliable basis and methodology and [were] simply [] *ipse dixit* opinion[s]." 948 F. Supp. 2d 589, 603-05 (S.D.W. Va. 2013). Keyes' OUD population estimate is in the same vein. There is no basis for Keyes' assumption that the risk of overdosing on fentanyl was no greater in 2018 than in 2015; indeed, that assumption runs counter to the evidence from the very sources on which she relies. That faulty assumption, in turn, causes Keyes to estimate a vastly larger OUD population than she would have found using a multiplier based on the 2018 data cited in her report.[40]

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[38] App. 137 (Keyes Rpt. 42).

[39] App. 137 (Keyes Rpt. 42); App. 80 (Keyes Dep. 316:14–317:1); App. 81 (*id.* at 318:5–19).

[40] App. 80 (Keyes Dep. 316:14–317:1); App. 81 (*id.* at 318:5–19).

B. Keyes' OUD Population Estimate Violates Two Core Requirements of Her Methodology.

Keyes' OUD population estimate is unreliable for a second reason: the method requires both a stable baseline population, and a multiplier that is based on that exact population. Both conditions are absent here.

Keyes testified that the multiplier method is "a methodology that's commonly used in [her] field."[41] While that may be true,[42] Keyes did not perform the calculation to the standards of others in her field. There are minimum requirements to the methodology that Keyes' calculation fails to satisfy.[43]

The first requirement for this methodology is that there is "a stable population" from which an extrapolation can be made.[44] "The assumptions of the multiplier method are all those outlined above, i.e., the population of problem drug users [1] needs to be stable and [2] the same during the benchmark recording as during the multiplier estimation."[45]

Keyes' OUD calculation does not satisfy this requirement. The statistic Keyes uses for her benchmark—overdose deaths from synthetic opioids in Cabell County—is highly variable over time. From 2011 to 2018, both the total number of overdose deaths in Cabell County

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41 App. 81 (Keyes Dep. 321:2–4).

42 Notably, the expert who *relies upon* Keyes' OUD estimate testified that this overdoses cannot be used to determine who has an addiction: "No, these data are overdose data, so you can't use overdose data to identify whether or not someone has addiction. No." App. 171 (Alexander Dep. 128:6–13).

43 App. 234 (M. Hickman & C. Taylor, *Indirect Methods to Estimate Prevalence* ("Hickman & Taylor") 118). Hickman is one of the co-authors of the paper Keyes identifies as "Larney et al." that is the source of the multiplier she uses. *See* App. 137 (Keyes Rpt. 42).

44 App. 234 (Hickman & Taylor at p. 118).

45 App. 236 (*id.* at p. 120) (emphasis added).

(ranging from a low of 41 to a high of 145), and the percentage involving synthetic opioids (ranging from a low of 10% to a high of 84%), underwent dramatic changes annually.[46] Given this instability, the multiplier method cannot provide a reliable estimate of the OUD population.[47]

A second requirement of the methodology is to have "[m]atching definitions,"[48] meaning "that the definition used for the benchmark is precise and ***matches exactly*** that used in estimating the multiplier."[49] "As an example of this latter point, if arrest data are used for the benchmark then the multiplier needs to find the proportion of drug users arrested, not those charged or sentenced. Or again, if a number of treatment clinics' records over one year is the benchmark, then the multiplier must relate to attendance at those clinics over that year."[50]

Keyes' calculation fails this requirement as well. The benchmark from which Keyes is attempting to extrapolate is "[i]n Cabell County, the number of drug overdoses in 2018 … attributable to synthetic opioids."[51] In contrast, she initially defined her multiplier as a rate of "overdose deaths from opioids, ***as well as other drugs***"—none of which were synthetic opioids

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[46] *See* App. 169 (Excerpt of Keyes MDL CT2 Input Calculations, Tab "Figure 13 and Table 2," at rows 10 and 17, columns H to O).

[47] App. 234, 236 (Hickman & Taylor, at pp. 118, 120); *see also* App. 174 (excerpt of expert report of Dr. Catherine Rahilly-Tierney), at p. 16) ("While the multiplier method has been traditionally used in the past to estimate the 'user pool' of persons with OUD, the death rate of persons with OUD is dynamic due to the intertwined fentanyl crisis in Cabell County, and its application here does not meet Hickman's requirement of population stability."). Dr. Rahilly-Tierney is Defendants' expert epidemiologist.

[48] App. 234 (Hickman & Taylor at p. 118).

[49] App. 236 (*id.* at p. 120) (emphasis added).

[50] App. 236–237 (*id.* at pp. 120–21).

[51] App. 137 (Keyes Rpt. 42).

like fentanyl.[52] Keyes modified that multiplier to attempt to account for fentanyl, but she did so using data concerning changes in the "overdose rate due to ***heroin and*** synthetic non-methadone opioids."[53] As a result, even as adjusted, the definition used for Keyes' benchmark population does not "match[] exactly that used in estimating the multiplier."[54] At a minimum, the multiplier is misaligned because it represents a blend of information about heroin and synthetic opioids, instead of synthetic opioids alone. Further, unlike her benchmark, the multiplier is not based on information specific to West Virginia, let alone Cabell County, notwithstanding significantly higher overdose death rates in the state and county.[55]

For both of these reasons, Keyes' calculation fails to satisfy basic prerequisites of the "multiplier method," and her opinion therefore fails the reliability test. *See, e.g., In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 745 (3d Cir. 1994) ("any step that renders the analysis unreliable … renders the expert's testimony inadmissible. This is true whether the step completely changes a reliable methodology or merely misapplies that methodology."); *Ky. Speedway, LLC v. NASCAR, Inc.*, 588 F.3d 908, 918 (6th Cir. 2009) (affirming exclusion of expert that made up his "own version" of a recognized methodology); *In re TMI Litig. Consol.*

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[52] App. 137 (Keyes Rpt. 42) (emphasis added).

[53] App. 137 (Keyes Rpt. 42) (emphasis added).

[54] App. 236 (Hickman & Taylor, at p. 120).

[55] The calculation results in wild swings in the estimated number of individuals suffering from OUD in Cabell County, further demonstrating the unreliability of Keyes' methodology. Keyes estimates that the number fell from 6,359 in 2011 to 3,763 in 2012—and then more than doubled in a single year, rising to 7,692 in 2013, before declining to 6,677 in 2014. App. 139 (Keyes Rpt. 44). This volatility in the Cabell County OUD population is facially implausible, and confirms that Keyes' failure to apply the multiplier method to a stable population using matching definitions results in unreliable outputs.

Cases, 911 F. Supp. 775, 825-26 (M.D. Pa. 1996) (excluding expert opinion because "[i]t is not a generally accepted practice to discard a key step in [a] standard methodology").

Conclusion

For the foregoing reasons the Court should exclude Keyes' opinions on the number of overdose deaths "directly" attributable to prescription opioids, and on the size of the 2018 OUD population in Cabell County.

Dated: October 2, 2020

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 2, 2020, the foregoing ***Defendants' Motion to Exclude Certain Expert Testimony of Katherine Keyes*** was filed using the Court's CM/ECF system, which will serve notification of such filing on all counsel of record.

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